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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,669	09/17/2003	Satoshi Omura	8012-1018-1	2478

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EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,669	<b>Applicant(s)</b> OMURA ET AL.	
	<b>Examiner</b> Elli Peselev	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,11 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 11 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claims 1, 5 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoeltje et al (U.S. Patent No. 5,418,224) for the reasons set forth in the Office Action of September 14, 2004.

Applicant's arguments filed February 11, 2005 have been considered but have not been found persuasive because the instant claims read on the reference's compound wherein R1 is I-Pr and R2 is H or Me. With respect to claim 23, Hoeltje et al disclose administration of the claimed compound. Differentiation-induction of a monocyte would have been inherent from such an administration.

Applicant contends that claim 1 has been amended to recite that wherein R1 is H or Me, R2 is not H, Me, or I-Pr. This argument has not been found persuasive.

Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 22 of prior U.S. Patent No. 6,734,292. This is a double patenting rejection.

Applicant's arguments filed February 11, 2005 have been considered but have not been found persuasive.

Applicant contends that claim 11 has been amended to recite that "wherein R3 is NOH, and Me indicates methyl". However, note that claim 22 also recites "wherein R3 is NOH, and Me indicates methyl".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje et al (U.S. Patent No. 5,418,224), Gidda et al (U.S. Patent No. 4, 920,102) or Kirst et al (U.S. Patent No. 5,106,961).

Each of Gidda et al and Kirst et al disclose closely analogous compounds and administration of said compounds wherein one or both R1 and R2 are methyl but do not disclose compounds wherein one or both R1 and R2 are ethyl. However, since ethyl is a next higher homologue of methyl, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to substitute ethyl for methyl on the references' compounds because such a person would have expected the resulting compounds to possess similar activity. Further, note that the terminology "treating said monocyte" (claim 23) encompasses administration of a compound to human since humans contain monocytes.

Claims 1, 5, 6 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje et al (U.S. Patent No. 5,418,224).

Hoeltje et al disclose a closely analogous compound wherein one of R1 and R2 is isopropyl and administration of said compound but do not disclose the claimed compounds wherein one or both R1 and R2 is n-propyl. However, since n-propyl is an isomer of isopropyl, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to substitute n-propyl for isopropyl in the reference's compound because such a person would have expected the resulting compounds to possess similar activity.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to describe what is meant by the term "substituents". See the reason stated in the Office Action of September 14, 2004.

Applicant's arguments filed February 11, 2005 have been considered but have not been found persuasive.

Applicant contends that the claims have been amended so that this terminology is no longer recited. This argument has not been found persuasive since claim 23 still recites the term "substituents".

Claims 1 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention. The terms "alkyl", "alkynyl" and "acyl" lack enablement. The only examples of alkyl group provided in the specification are methyl, ethyl and propyl. The only example of an alkynyl group provided in the specification is allyl. The only example of acyl group provided in the specification is acetyl. The specification fails to provide any definition of the terms alkyl, alkynyl and acyl. Note that said substituents are not limited to any number of carbon atoms and encompass substituents having more than 20 carbon atoms. The disclosure of substituents having 1, 2 or 3 carbon atoms does not provide an adequate support for claiming substituents having more than 20 carbon atoms. Note that a person having ordinary skill in the art at the time the instant invention was made would not have expected a compound substituted by, for example, an alkyl having 3 carbon atoms to have similar activity to a compound substituted by an alkyl having 20 carbon atoms.

Claims 4, 6 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "monocyte" (claim 23, line 2 is misspelled).

It is not clear why there are spaces in the names of compounds as set forth in claims 4 and 6.

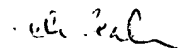
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1201**